

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY  
DEPARTMENT OF PESTICIDE REGULATION

MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA

MINERAL OIL - **PETROLEUM HYDROCARBONS**

Chemical Code # 473, Tolerance # 50444, SB 950 # 789

Original date: 7/19/01

I. DATA GAP STATUS

Chronic, rat:	Data gap, no study on file
Chronic, dog:	Data gap, no study on file
Oncogenicity, rat:	Data gap, no study on file
Oncogenicity, mouse:	Data gap, inadequate study, possible adverse effect indicated
Reproduction, rat:	Data gap, no study on file
Teratology, rat:	Data gap, no study on file
Teratology, rabbit:	Data gap, no study on file
Gene mutation:	Data gap, inadequate study, no adverse effect indicated
Chromosomal aberration:	Data gap, no study on file
DNA damage:	Data gap, no study on file
Neurotoxicity:	Not required at this time

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Toxicology one-liners are attached.

**Bold face** indicates a possible adverse effect.

\*\* indicates an acceptable study.

File name: T010719

Original: J. Gee, 11/2/87

Revised: Silva, 9/88; Kishiyama & Silva, 7/19/01

All record numbers through 052436 were examined.

## II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

These pages contain summaries only. Individual worksheets may contain additional effects.

### COMBINED, RAT

No study submitted

### CHRONIC TOXICITY, RAT

No study submitted

### CHRONIC, DOG

No study submitted

### ONCOGENICITY, RAT

No study submitted

### ONCOGENICITY, MOUSE

**50444 - 003 052436** “Toxicology and Carcinogenesis Studies of Marine Diesel Fuel and JP-5 Navy Fuel in B6C3F<sub>1</sub> Mice”. (Litton Bionetics, Inc.; National Toxicology Program Technical Report Series #: 310; NIH Publication #: 86-2566; 9/86). JP-5 navy and marine diesel fuels were administered to B6C3F<sub>1</sub> mice (50/sex/dose) as daily (5d/week) dermal treatments for 103 weeks at 0 (acetone), 250 and 500 mg/kg. Systemic NOEL < 250 mg/kg (Both treatments increased the death rate of mice. Marine diesel and JP-5 navy fuel treatments decreased bodyweights at 500 mg/kg. At 250 mg/kg, both fuels induced decreased bodyweights. Both fuels at both doses increased the incidence of skin irritation (ulcers & chronic dermatitis) at the treatment site. Splenic hematopoiesis, plasmacytosis of the axillary lymph node at  $\geq$  250 mg/kg and amyloidosis (many organs) at 500 mg/kg in females were due to severe dermatitis and skin ulceration. Liver hematopoiesis (females, 500 mg/kg) and urinary bladder inflammatory infiltrates at 500 mg/kg in both sexes, were observed. JP-5 Navy Fuel increased the incidence of amyloid (kidney, adrenal cortex, spleen, and multiple organs) in males at 500 mg/kg and in females (spleen, kidney, multiple organs) at 500 mg/kg due to severe dermatitis and skin ulceration. Granulocytic hyperplasia of bone marrow in males at 500 mg/kg and hyperplasia of axillary lymph nodes in females at 500 mg/kg were observed.) Oncogenicity NOEL < 250 mg/kg (**Possible adverse effect indicated:** Marine diesel fuel at  $\geq$  250 mg/kg increased the incidence in squamous cell carcinomas at the treatment site as well as hepatocellular adenoma and carcinoma in males. No evidence of carcinogenicity with JP-5 navy fuel treatments. UNACCEPTABLE (Not a FIFRA Guideline study). These data are supplemental. (Kishiyama & Silva, 5/31/01).

The following three (3) studies contributed toward dose selection for the above study 003 052436.

#### **Acute Dermal:**

50444 - 003 052433 “Single Dermal administration Study of Marine Diesel Fuel in B6C3F<sub>1</sub> Mice,” (Litton Bionetics, Inc; National Toxicology Program Technical Report Series #: 310; NIH Publication #: 86-2566; 9/86). Marine diesel fuel was administered 1 time dermally to B6C3F<sub>1</sub> mice (5/sex/dose) at 5,000, 10,000, 20,000, 30,000 or 40,000 (the neat chemical) mg/kg. No reported treatment related effects occurred. No

adverse effect indicated. Unacceptable (supplementary data). (Kishiyama & Silva, 12/7/01)

### Primary Dermal Irritation:

50444 - 003 052434 "A Fourteen Day Dermal Administration Study of Marine Diesel Fuel and JP-5 Navy Fuel in B6C3F<sub>1</sub> Mice," (Litton Bionetics, Inc.; National Toxicology Program Technical Report Series #: 310; NIH Publication #: 86-2566; 9/86). Marine diesel (MDF) and JP-5 Navy fuel was dermally administered for 14 days to B6C3F<sub>1</sub> mice (5/sex/dose). MDF treatment was 0 (95% ethanol), 2000, 4000, 8000, 20000 or 40000 (the neat chemical) mg/kg and JP-5 Navy fuel treatment was 0 (95% ethanol), 5000, 10000, 20000, 30000 or 40000 mg/kg. Mortality was 100% for all mice at  $\geq$  20000 mg/kg MDF. Mortality was 100% for JP-5 Navy fuel at  $\geq$  30000 mg/kg in females and at 40000 mg/kg in males. Acanthosis, hyperkeratosis and dermal inflammation occurred at the treatment site for all dosed groups. UNACCEPTABLE (supplemental data; no worksheet). (Kishiyama & Silva, 12/7/01)

### Subchronic Study:

**50444 - 003 052435** "A 13-Week Dermal Administration Study of Marine Diesel Fuel and JP-5 Navy Fuel in B6C3F<sub>1</sub> Mice," (Litton Bionetics, Inc.; National Toxicology Program Technical Report Series #: 310; NIH Publication #: 86-2566; 9/86). Marine diesel (MDF) and JP-5 Navy fuel was dermally administered for 13 weeks to B6C3F<sub>1</sub> mice (10/sex/dose). MDF was used at 0 (acetone), 250, 500, 1000, 2000 or 4000 (applied neat) mg/kg and JP-5 Navy fuel was used at 0 (acetone), 500, 1000, 2000, 4000 or 8000 (applied neat) mg/kg. Mortality was 0% for males and 50% for female at 4000 mg/kg DMF. Mortality was 50% for males and 0% for females at 8000 mg/kg JP-5 Navy fuel, but was 40% and 50% at 2000 and 4000 mg/kg, respectively with JP-5 navy fuel treatment. Male body weights were decreased 8-13% at 500 to 4000 mg/kg DMF and were decreased 4-7% at 2000 to 8000 mg/kg JP-5 navy fuel. Active dermatitis at the treatment site was reported at 4000 mg/kg DMF and at all concentrations of JP-5 navy fuel. Possible adverse effect indicated: **The incidence of splenic extramedullary hematopoiesis and liver karyomegaly increased with JP-5 navy fuel at  $\geq$  1000 mg/kg.** Not acceptable (Not a FIFRA Guideline study). These data are supplemental. (Kishiyama & Silva, 12/7/01).

### REPRODUCTION, RAT

No study submitted

### TERATOLOGY, RAT

No study submitted.

### TERATOLOGY, RABBIT

No study submitted

### GENE MUTATION

50444 - 003 052436 "Mutagenicity of Marine Diesel and JP-5 Navy Fuel in *Salmonella typhimurium*," (National Toxicology Program, National Toxicology Program: TR 310; Research Triangle Park, Raleigh, NC; 9/86). Marine diesel fuel was evaluated for mutagenicity at concentrations ranging from 3 to 3333  $\mu$ g/plate (+ & - hamster and rat S9) using *Salmonella typhimurium* strains TA100, TA1535, TA1537 and TA98 and with JP-5 navy fuel (+/- S9) at 10 to 10000  $\mu$ g/plate using strains TA100, TA1535, TA97 and TA98. Cells were preincubated 20 minutes before plating in agar. There were two trials with triplicate plates. No evidence of mutagenicity was observed. This was not a FIFRA Guideline study. These data are supplemental.

UNACCEPTABLE (no positive controls and insufficient information). (Kishiyama & Silva, 5/31/01).

#### CHROMOSOME EFFECTS

No study submitted.

#### DNA DAMAGE

No study submitted